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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 10/727,646 | 12/05/2003 | Isaac Rothman | 440833 | 8973 |

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| EXAMINER |
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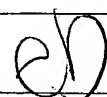
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| ART UNIT | PAPER NUMBER |
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1723

DATE MAILED: 04/20/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|--|--------------------------------------|---------------------------------------|---|
| <p align="center">Office Action Summary</p> | Application No. 10/727,646 | Applicant(s) ROTHMAN ET AL. | |
| | Examiner John Kim | Art Unit 1723 |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 December 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-25 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-25 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 05 December 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date <u>12/5/03</u> . | 6) <input type="checkbox"/> Other: _____ |

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1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 1-4, 8, 10 and 16-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,544,727 (hereinafter referred to as Hei) in view of European Patent Application No. 2230247 (hereinafter referred to as EP '247). Hei teaches a biological fluid processing set comprising at least two flexible containers including ports and containing platelets and a filter comprising adsorbents within a mesh enclosure in the bag for removing psoralens (see figures 37-38B, 47-51; col. 7, line 26 – col. 8, line 43; col. 12, lines 33-57; col. 13, line 21 – col. 14, line 49; col. 42, line 1 – col. 43, line 62; col. 48, line 53 – col. 49, line 55; col. 52, line 1 – col. 53, line 35; col. 54, lines 32-41; Table BB in col. 56; col. 59, lines 21-45; col. 122, line 43 – col. 123, line 48). Hei further teaches that apheresis platelets are added to a container housing the adsorbents, inherently contacting the platelets with the adsorbents for requisite period of time for removing psoralens from the apheresis platelets wherein platelets are agitated in the bag with adsorbents for period of 8 hours on a shaker and treated platelets are removed to a storage container to be used in less than 4 days and no more than 5 days after withdrawal of whole blood from the donor (see col. 66, line 24 – col. 68, line 67; col. 141, line 45 – col. 142, line 22). Claims 1-4, 8, 10 and 16-23 essentially differ from the apparatus and method of Hei in reciting the use of complement filter. EP '247 teaches an adsorbent for removing complement component from body fluid including fraction of blood inherently including platelets (see page 2,

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lines 1-5; 41-48). It would have been obvious to a person of ordinary skill in the art at the time the invention was made to use adsorbents for removing complements for adsorbents in the apparatus and method of Hei for removing complements from apheresis platelets.

3. Claim 25 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hei in view of EP '247 as applied to claim 16 above, and further in view of U.S. Patent No. 5,427,695 (hereinafter referred to as Brown). Hei in view of EP '247 teaches the method of removing complements from apheresis platelets. Claim 25 essentially differs from the method of Hei in view of EP '247 in reciting that the apheresis platelets are leukocyte-depleted apheresis platelets. Brown teaches the apheresis method including the step of removing leukocytes from platelet rich plasma (PRP) to obtain leukocyte depleted platelet rich plasma (LDPRP) and separating LDPRP into leukocyte depleted platelet concentrate (LDPC) and platelet poor plasma (see figures 1, 6-7; col. 3, line 45 – col. 4, line 52). It would have been obvious to a person of ordinary skill in the art at the time the invention was made to treat LDPC with complement filter in a platelet storage bag in the method of Hei in view of EP '247 to remove complements from LDPC.

4. Claims 1-2, 5-10, 14-17, 21 and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 93/04763 (hereinafter referred to as WO '763) in view of U.S. Patent No. 5,695,489 (hereinafter referred to as Japuntich). WO '763 teaches a container containing an filter for removing complement C3a wherein the filter is made of membrane and having a pore rating about 0.5 micron to about 50 microns and the optimization of the pore rating of the porous medium for a particular use will be well understood by those skilled in the art (see page 3, line 19 - page 4, line 33; page 8, lines 20-30; page 11, lines 10-29; page 14, lines 1-34; page 15, lines 8-17; page 17, lines 18-35; page 18, lines 13-29; page 26, lines 1-7; page 33, lines 10-27). WO

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'763 further teaches that the filter is used to treat various blood and/or blood components including platelet concentrate (page 14, lines 1-13; page 33, lines 10-26). Claims 1-2, 5, 10 and 14-17 and 21 essentially differ from the apparatus of WO '763 in reciting at least two flexible containers. Japuntich teaches a flexible blood bag containing filtering material for filtering biological fluid (see col. 1, line 65 - col. 2, line 10; col. 2, line 38 - col. 3, line 60). It would have been obvious to a person of ordinary skill in the art at the time the invention was made to include filtering material of WO '763 in a known-known flexible containers such as blood bags for removing complement from blood. Claims 6-9 recite various ways that filters can be contained in a container including the filter being secured to an inner wall of the container, tethered to the container or not secured to the container or in a side seal of the container. WO '763 teaches that filter can be used in various forms and various ways. Japuntich teaches that filter are attached and/or supported in the flexible container in various ways with separating means (see col. 1, line 1 - col. 2, line 10; col. 3, line 61 - col. 5, line 3; figures 1-7). Claimed modes of the attaching or not attaching filter in claims 6-10 are well-known in the art and would have been obvious to a person of ordinary skill in the art to modify the structural attachment of the filter to a container for the intended use of the filter such as filter laid in a container to remove complement in a biological fluid in a container.

5. Claims 11-13 and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO '763 in view of Japuntich as applied to claims 1 and 16 above, and further in view of EPA '247. Claim 11-13 and 24 essentially differ from the apparatus and method of WO '763 in view of Japuntich in reciting that a membrane has anionic groups bound to the surface of membrane including carboxylic groups and having a negative zeta potential at physiological pH. WO '763

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teaches that gas plasma is used to modify the properties of membrane to improve its biocompatibility and ability to selectively remove various cellular, particulate and dissolved material (page 12, lines 23-31). EPA '247 teaches that any anionic groups can be attached to the surface of gel in a shape of inherent membrane so long as the groups are charged with negative electricity in pH value around neutrality and anionic groups provides strong affinity for the complement component (see page 3, lines 42-54). It would have been obvious to a person of ordinary skill in the art at the time the invention was made to modify the apparatus of WO '763 in view of Japuntich to incorporate anionic groups including carboxylic groups into the membrane to improve affinity for complement components to remove them out of platelet containing biological fluid.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to John Kim whose telephone number is (571) 272-1142. The examiner can normally be reached on weekdays from 7:00 AM - 3:00 PM.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Wanda Walker, can be reached on (571) 272-1151. The fax phone number for official response is (703) 872-9306.

When sending a draft amendment by fax, please mark the paper as "DRAFT"; otherwise, mark the paper "OFFICIAL". This will expedite the processing of the paper.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0651.

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John Kim
Primary Examiner
Art Unit 1723

J. Kim
April 15, 2004